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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/459,774	12/13/99	BARNES M	GP-30193

HM22/0615

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EXAMINER	
ZEMAN, R	
ART UNIT	**PAPER NUMBER**
1645	8

DATE MAILED: 06/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/459,774	Barnes et al.
Examiner	**Group Art Unit**
Robert A. Zeman	1645

☒ Responsive to communication(s) filed on *Dec 13, 1999* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-10* is/are pending in the application.

Of the above, claim(s) *1, 3, 4, and 10* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *2 and 5-9* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-10* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *6*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Election/Restriction

Applicant's election of group II in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1, 3-4 and 10 are withdrawn from consideration as they are drawn to a non-elected invention. Claims 2 and 5-9 are pending and currently under examination.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: **Human WNT7a polynucleotides**

Claim Objections

Claims 5-9 are objected to as being dependent upon a non-elected claim. Claims 5 and 6 should be rewritten in independent form including all of the limitations of the base claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides with at least a 99.5% sequence identity with SEQ ID NO:1 and polynucleotides that encode for polypeptides with at least 99% identity with SEQ ID NO:2, does not reasonably provide enablement for "variants and fragments" of RNA complementary to the aforementioned polynucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Applicant fails to define what is meant by a "variant". The specification is silent on what percentage of divergence is required to be considered a variant and at what point does a "variant" become totally unrelated. The specification is equally deficient is defining what is meant by a "fragment". Applicant fails to disclose what percentage of the total sequence must be present in order for a nucleotide to be considered a fragment of said polynucleotide or what biochemical/hybridizational properties must be present in order for a polynucleotide to be considered a "fragment". Consequently, it would be impossible for one of skill in the art to ascertain what would fall under the categories of "variant" or "fragment".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is rendered vague and indefinite by the use of improper Markush language. It is suggested that section (j) of said claim be amended as follows: "a polynucleotide which is the RNA equivalent of a polynucleotide of (a) to (i); a polynucleotide sequence complementary to said isolated polynucleotide; a polynucleotide sequence complementary to polynucleotides that are variants and fragments of the above mentioned polynucleotides; **and** a polynucleotide sequence complementary to the abovementioned polynucleotides over the entire length thereof.

Claim 2 is rendered vague and indefinite by the use of the term "variants and fragments" in the penultimate line of said claim. It is unclear what Applicant means by said term. What constitutes a fragment? 10 amino acids? 20 amino acids? What percentage of sequence identity must be shared in order to be considered a "variant"? 90%? 50%? As written it is impossible to determine the metes and bounds of the claimed invention.

Use of the term "capable of " renders claims 5 and 6 vague and indefinite. Having the capacity to do something does not mean that it is actually being done. Consequently, it is impossible to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Ikegawa et al. (Cytogenetics and Cell Genetics, 1996 Vol. 74 pages 149-152).

Ikegawa et al. disclose a nucleic acid sequence for **human WNT7a** that is 99.5% identical to the nucleic acid of the claimed invention and an amino acid sequence that is 99.4% identical to the polynucleotide of the claimed invention (see Figure 1 on page 150 and STIC sequence search report, attached). Consequently, Ikegawa et al. clearly anticipate all the elements of the claimed invention.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Bui et al. (Gene Vol. 189 pages 25-29, 1997, IDS-6).

Bui et al. disclose a nucleic acid sequence for **human WNT7a** that is 98.9 identical to the claimed invention and therefore a "variant" said invention (see Figure 2 on page 27 and STIC sequence search report, attached). Consequently, Bui et al. clearly anticipate all the elements of the claimed invention.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Gavin et al. (Genes and Development Vol. 4 pages 2319-2322, 1990).

Gavin et al. disclose a nucleic acid sequence for **murine WNT7a** that is 88.3 identical to the claimed invention and therefore a "variant" said invention (see STIC sequence search report, attached). Consequently, Gavin et al. clearly anticipate all the elements of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikegawa et al. (Cytogenetics and Cell Genetics ,1996 Vol. 74 pages 149-152), as applied to claim 2, above, in view of Sambrook et al. (Molecular Cloning A Laboratory Manual Second Edition. Cold Spring Harbor Laboratory Press, Plainview, New York. 1989).

Ikegawa et al. disclose the nucleic acid sequence and amino acid sequence for the human WNT7a protein. Said sequences are 99.5% and 99.4% identical to the claimed invention (see STIC search report, attached). Ikegawa et al. differs from the claimed invention in that they do not disclose an expression vector containing the sequence for the claimed polynucleotide (WNT7a), a recombinant cell with said vector (and therefore, the cell membranes of said cells) , or a method for producing the WNT7a protein using said vector and recombinant cell. Sambrook et al. disclose detailed conventional methods for the production of expression vectors (see pages 16.5-16.16), vector systems (see pages 16.17-16.28) and Amplification systems (cell lines expressing proteins from foreign nucleic acids) [see pages 16.28-16.55]. Consequently, it would have been obvious to one of skill in the art to use the nucleotide sequence disclosed by Ikegawa et al. in the methods for expression of proteins from cloned genes in mammalian cells disclosed by Sambrook et al. because Ikegawa et al. establishes the interest in the WNT7a gene and since said methods are methods are common laboratory practices. Additionally, as Sambrook et al. state "expression of proteins from cloned eukaryotic genes in mammalian cells has been used for a number of different purposes". These purposes include: confirming the identity of a cloned gene by using immunological or functional assays to detect the encoded protein; to express genes encoding proteins that require posttranslational modification; to produce large amounts of proteins that are normally available in limited amounts; to study the biosynthesis and intracellular transport of proteins following their expression in various cell types; to elucidate structure-function relationships by analyzing the properties of normal and mutant proteins; to express

intron-containing genomic sequences that cannot be transcribed correctly into mRNA in prokaryotes or yeasts; and to identify DNA sequence elements involved in the control of gene expression. The aforementioned uses for the disclosed methods of Sambrook et al. demonstrate the widespread use of said methods and therefore, would not only have been obvious for one of skill in the art to use said methods in conjunction with the sequences disclosed by Ikegawa et al., said artisans would have had more than a reasonable expectation of success.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Anthony Caputa, can be reached at (703)308-3995.

Robert A. Zeman

June 14, 2000

DONNA WORTMAN
PRIMARY EXAMINER